

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Examiner:

Unassigned

Steven Z. Wu et al.

Serial No.

10/663,181

Art Unit:

Unassigned

Filed:

September 15, 2003

Title:

Microparticle Coated Medical Device

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§1.97-1.98

## Dear Examiner:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and pursuant to 37 C.F.R. §\$1.97-1.98, Applicants hereby notify the U.S. Patent and Trademark Office of the references listed on the attached Form PTO-1449. According to a Notice signed July 11, 2003, the U.S. Patent and Trademark Office has waived the requirement under 37 C.F.R. § 1.98(a)(2)(i) for all patent applications filed after June 30, 2003. Since this patent application was filed after June 30, 2003, Applicants have not provided copies of the cited U.S. patents. Copies of the cited foreign patent documents and non-patent literature have been submitted herewith.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants reserve the right to dispute the listed documents as prior art during examination. Furthermore, Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application. The submission of this Information Disclosure Statement is not to be construed as a representation that a search has been made or that no other material information may exist.

The Examiner is requested to initial the enclosed Form PTO-1449 and return a copy thereof to the undersigned.

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The present Information Disclosure Statement is being filed before receiving the first Office Action. Therefore, no certification under 37 C.F.R. §1.97(e) or fee under 37 C.F.R. §1.17(p) is required. However, the Commissioner is authorized to charge any deficiencies or other amounts due to Deposit Account No. 07-1850.

Date: October  $\frac{19}{1}$ , 2

SQUIRE, SANDERS & DEMPSEY L.L.P. One Maritime Plaza, Suite 300 San Francisco, CA 94111 Telephone (415) 954-0200 Facsimile (415) 393-9887 Respectfully submitted,

Paul J. Meyer, Jr.

Attorney for Applicants

Reg. No. 47,791

US DEPARTMENT OF COMMERCE

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US Patent and Trademark Office

Docket No. Application No. 50623.334 10/663,181

INFORMATION DISCLOSURE CITATION Applicant

in an Application
(Use several sheets if necessary)

Steven Z. Wu

Filing Date

Group Art Unit

September 15, 2003

Unassigned

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
	A1	4,329,383	5/11/82	Joh	428	36	
	A2	4,733,665	3/29/88	Palmaz	128	343	
	А3	4,800,882	1/31/89	Gianturco	128	343	-
	A4	4,882,168	11/21/89	Casey et al.	424	468	
	A5	4,886,062	12/12/89	Wiktor	128	343	
	A6	4,941,870	7/17/90	Okada et al.	600	36	
	A7	4,977,901	12/18/90	Ofstead	128	772	
	A8	5,112,457	5/12/92	Marchant	204	165	
	A9	5,165,919	11/24/92	Sasaki et al.	424	488	
	A10	5,272,012	12/21/93	Opolski	428	423.1	
	A11	5,292,516	3/8/94	Viegas et al.	424	423	
	A12	5,298,260	3/29/94	Viegas et al.	424	486	
	A13	5,300,295	4/5/94	Viegas et al.	424	427	
	A14	5,306,501	4/26/94	Viegas et al.	424	423	
	A15	5,328,471	7/12/94	Slepian	604	101	
	A16	5,330,768	7/19/94	Park et al.	424	501	
	A17	5,380,299	1/10/95	Fearnot et al.	604	265	
	A18	5,417,981	5/23/95	Endo et al.	424	486	
	A19	5,447,724	9/5/95	Helmus et al.	424	426	
	A20	5,455,040	10/3/95	Marchant	424	426	
	A21	5,462,990	10/31/95	Hubbell et al.	525	54.1	
	A22	5,464,650	11/7/95	Berg et al.	427	2.30	
	A23	5,569,463	10/29/96	Helmus et al.	424	426	
AMINER	<u>-</u>			DATE CONSIDERED			

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Filing Date September 15, 2003 Group Art Unit
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**U.S. PATENT DOCUMENTS** 

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date i Appropriate
	A24	5,578,073	11/26/96	Haimovich et al.	623	1	
	A25	5,605,696	2/25/97	Eury et al.	424	423	·.—
	A26	5,609,629	3/11/97	Fearnot et al.	623	1	
	A27	5,624,411	4/29/97	Tuch	604	265	
	A28	5,628,730	5/13/97	Shapland et al.	604	21	
	A29	5,649,977	7/22/97	Campbell	623	1	
	A30	5,658,995	8/19/97	Kohn et al.	525	432	
	A31	5,665,382	9/9/97	Grinstaff et al.	424	450	
	A32	5,667,767	9/16/97	Greff et al.	424	9.411	
	A33	5,670,558	9/23/97	Onishi et al.	523	112	
	A34	5,679,400	10/21/97	Tuch	427	2.14	
	A35	5,700,286	12/23/97	Tartaglia et al.	623	1	· <u>-</u>
	A36	5,702,754	12/30/97	Zhong	427	2.12	- <del></del>
	A37	5,716,981	2/10/98	Hunter et al.	514	449	
	A38	5,735,897	4/7/98	Buirge	623	12	
	A39	5,746,998	5/5/98	Torchilin et al.	424	9.4	
	A40	5,776,184	7/7/98	Tuch	623	1	
	A41	5,788,979	8/4/98	Alt et al.	424	426	
	A42	5,800,392	9/1/98	Racchini	604	96	
	A43	5,820,917	10/13/98	Tuch	427	2.1	.=
	A44	5,824,048	10/20/98	Tuch	623	1	
	A45	5,824,049	10/20/98	Ragheb et al.	623	1	

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Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate			
	A46	5,830,178	11/3/98	Jones et al.	604	49				
	A47	5,837,008	11/17/98	Berg et al.	623	1				
	A48	5,837,313	11/17/98	Ding et al.	427	2.21				
	A49	5,851,508	12/22/98	Greff et al.	424	9.411				
	A50	5,858,746	1/12/99	Hubbell et al.	435	177				
	A51	5,865,814	2/2/99	Tuch	604	265				
	A52	5,869,127	2/9/99	Zhong	427	2.12				
	A53	5,873,904	2/23/99	Ragheb et al.	623	1	. <del></del> .			
	A54	5,876,433	3/2/99	Lunn	623	1				
	A55	5,877,224	3/2/99	Brocchini et al.	514	772.2				
	A56	5,925,720	7/20/99	Kataoka et al.	525	523				
	A57	5,955,509	9/21/99	Webber et al.	514	772.7				
	A58	5,971,954	10/26/99	Conway et al.	604	96				
	A59	5,980,928	11/9/99	Terry	424	427				
	A60	5,980,972	11/9/99	Ding	427	2.24				
	A61	5,997,517	12/7/99	Whitbourne	604	265				
	A62	6,010,530	1/4/00	Goicoechea	623	1				
	A63	6,015,541	1/18/00	Greff et al.	424	1.25				
	A64	6,033,582	3/7/00	Lee et al.	216	37				
	A65	6,042,875	3/28/00	Ding et al.	427	2.24				
	A66	6,051,648	4/18/00	Rhee et al.	525	54.1				
	A67	6,051,576	4/18/00	Ashton et al.	514	255				
	A68	6,056,993	5/2/00	Leidner et al.	427	2.25				
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18A	U.S. PATENT DOCUMENTS						
Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
	A69	6,060,451	5/9/00	DiMaio et al.	514	13	
	A70	6,060,518	5/9/00	Kabanov et al.	514	781	
	A71	6,080,488	6/27/00	Hostettler et al.	428	423.3	
	A72	6,096,070	8/1/00	Ragheb et al.	623	1	
	A73	6,099,562	8/8/00	Ding et al.	623	1.46	
	A74	6,110,188	8/29/00	Narciso, Jr.	606	153	
	A75	6,110,483	8/29/00	Whitbourne et al.	424	423	
	A76	6,113,629	9/5/00	Ken	623	1.1	
	A77	6,120,536	9/19/00	Ding et al.	623	1.43	
	A78	6,120,904	9/19/00	Hostettler et al.	428	423.3	
	A79	6,121,027	9/19/00	Clapper et al.	435	180	
	A80	6,129,761	10/10/00	Hubbell	623	11	
	A81	6,153,252	11/28/00	Hossainy et al.	427	2.3	
	A82	6,165,212	12/26/00	Dereume et al.	623	1.13	
	A83	6,203,551	3/20/01	Wu	606	108	
	A84	6,231,600	5/15/01	Zhong	623	1.42	
	A85	6,240,616	6/5/01	Yan	29	527.2	
	A86	6,245,753	6/12/01	Byun et al.	514	56	
	A87	6,251,136	6/26/01	Guruwaiya et al.	623	1.46	
	A88	6,254,632	7/3/01	Wu et al.	623	1.15	
	A89	6,258,121	7/10/01	Yang et al.	623	1.46	
	A90	6,283,947	9/4/01	Mirzaee	604	264	
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U.S. PATENT DOCUMENTS							
Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
	A91	6,283,949	9/4/01	Roorda	604	288.02	
	A92	6,284,305	9/4/01	Ding et al.	427	2.28	
	A93	6,287,628	9/11/01	Hossainy et al.	427	2.3	
	A94	6,299,604	10/9/01	Ragheb et al.	604	265	
	A95	6,306,176	10/23/01	Whitbourne	623	23.59	
	A96	6,331,313	12/18/01	Wong et al.	424	427	
	A97	6,335,029	1/1/02	Kamath et al.	424	423	
	A98	6,346,110	2/12/02	Wu	606	108	
	A99	6,358,556	3/19/02	Ding et al.	427	2.24	
	A100	6,379,381	4/30/02	Hossainy et al.	623	1.42	
	A101	6,395,326	5/28/02	Castro et al.	427	2.24	
	A102	6,419,692	7/16/02	Yang et al.	623	1.15	
	A103	6,451,373	9/17/02	Hossainy et al.	427	2.25	8/4/00
	A104	6,494,862	12/17/02	Ray et al.	604	96.01	12/30/99
	A105	6,503,556	1/7/03	Harish et al.	427	2.24	12/28/00
	A106	6,503,954	1/7/03	Bhat et al.	514	772.2	7/21/00
	A107	6,506,437	1/14/03	Harish et al.	427	2.25	10/17/00
	A108	6,527,801	3/4/03	Dutta	623	1.46	4/13/00
	A109	6,527,863	3/4/03	Pacetti et al.	118	500	6/29/01
	A110	6,540,776	4/1/03	Sanders Millare et al.	623	1.15	12/28/00

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Filing Date

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Examiner Initial	, ,		Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
	A111	6,544,223	4/8/03	Kokish	604	103.01	1/5/01
	A112	6,544,543	4/8/03	Mandrusov et al.	424	422	12/27/00
	A113	6,544,582	4/8/03	Yoe	427	2.24	1/5/01
	A114	6,555,157	4/29/03	Hossainy	427	2.24	7/25/00
	A115	6,558,733	5/6/03	Hossainy et al.	427	2.24	10/26/00
	A116	6,565,659	5/20/03	Pacetti et al.	118	500	6/28/01
· '-' -1_ · · · · · · · · · · · · · · · · · · ·	A117	6,572,644	6/3/03	Moein	623	1.11	6/27/01
··, ··,	A118	6,585,765	7/1/03	Hossainy et al.	623	1.45	6/29/00
	A119	6,585,926	7/1/03	Mirzaee	264	400	8/31/00
· · · · · · · · · · · · · · · · · · ·	A120	6,605,154	8/12/03	Villareal	118	500	5/31/01
	<u>l </u>	U.S. PATE	NT APPLICAT	TION PUBLICATION DOCU	MENTS		
Examiner Initial	Ref. No.	Document Number	Date of Publication	Name	Class	Subclass	Filing Date if Appropriate
	A121	2001/0018469	8/30/01	Chen et al.	523	121	
	A122	2001/0037145	11/1/01	Guruwaiya et al.	623	1.15	
	A123	2002/0077693	6/20/02	Barclay et al.	623	1.13	
	A124	2002/0091433	7/11/02	Ding et al.	623	1.2	
	A125	2002/0155212	10/24/02	Hossainy	427	2.25	4/24/01
	A126	2003/0065377	4/3/03	Davila et al.	623	1.13	4/30/02
	A127	2003/0099712	5/29/03	Jayaraman	424	486	11/26/01
XAMINER				DATE CONSIDERED			

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Examiner Initial	Ref. No.	. No. Document	Date of Country Publication	Country	Class	Subclass	Translation	
		Number					Yes	No
	B1	EP 0 301 856	2/1/89	European				
	B2	EP 0 514 406	11/25/92	European				
	В3	EP 0 604 022	6/29/94	European				
	B4	EP 0 623 354	11/9/94	European				
	B5	EP 0 665 023	8/2/95	European				
	B6	EP 0 701 802	3/20/96	European				
	В7	EP 0 716 836	6/19/96	European				:
	В8	EP 0 809 999	12/3/97	European				l
	В9	EP 0 832 655	4/1/98	European				
	B10	EP 0 850 651	7/1/98	European				La.
	B11	EP 0 879 595	11/25/98	European				ı
	B12	EP 0 910 584	4/28/99	European				I
	B13	EP 0 923 953	6/23/99	European				ı
	B14	EP 0 953 320	11/3/99	European				
	B15	EP 0 970 711	1/12/00	European				ı
	B16	EP 0 982 041	3/1/00	European				
	B17	EP 1 273 314	1/8/03	European				
	B18	2001-190687	7/17/01	Japan (Abstract)			Х	
	B19	WO 91/12846	9/5/91	РСТ				
	B20	WO 95/10989	4/27/95	РСТ			-	
	B21	WO 96/40174	12/19/96	PCT				

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Examiner	Ref. No.	o. Document	ent Date of	Country	Class	Subclass	Translatio	
Initial		Number	Publication		_		Yes	No
	B22	WO 97/10011	3/20/97	PCT				
-	B23	WO 97/45105	12/4/97	PCT				
	B24	WO 97/46590	12/11/97	PCT				
	B25	WO 98/17331	4/30/98	PCT				
	B26	WO 98/36784	8/27/98	PCT				
	B27	WO 99/01118	1/14/99	PCT				
	B28	WO 99/38546	8/5/99	PCT				
	B29	WO 99/63981	12/16/99	PCT				
	B30	WO 00/02599	1/20/00	PCT				
	B31	WO 00/12147	3/9/00	PCT				
· · · · · · · · · · · · · · · · · · ·	B32	WO 00/18446	4/6/00	PCT				
	B33	WO 00/64506	11/2/00	PCT				
	B34	WO 01/01890	1/11/01	PCT		:		
	B35	WO 01/15751	3/8/01	PCT				
	B36	WO 01/17577	3/15/01	PCT				
	B37	WO 01/45763	6/28/01	PCT				
	B38	WO 01/49338	7/12/01	PCT				
	B39	WO 01/74414	10/11/01	PCT				
	B40	WO 02/03890	1/17/02	PCT				
	B41	WO 02/026162	4/4/02	PCT				
	B42	WO 02/34311	5/2/02	PCT				_
	B43	WO 02/056790	7/25/02	PCT				
	B44	WO 03/000308	1/3/03	PCT				

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FORM RTD-1449 (Modified) US DEPARTMENT OF COMMERCE Docket No. Application No. 50623.334 10/663.181 App 6 ved for use through 10/31/2002 US Patent and Trademark Office INFORMATION DISCLOSURE CITATION Applicant Steven Z. Wu in an Application Filing Date Group Art Unit (Use several sheets if necessary) September 15, 2003 Unassigned FOREIGN PATENT DOCUMENTS Class Subclass Translation Examiner Ref. No. Document Date of Country Yes Initial Number **Publication B45** WO 03/022323 3/20/03 PCT B46 WO 03/028780 4/10/03 **PCT** PCT **B47** WO 03/037223 5/8/03 **B48** WO 03/039612 5/15/03 **PCT** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) C1 Anonymous, Cardiologists Draw - Up The Dream Stent, Clinica 710:15 (June 17, 1996), http://www.dialogweb.com/cgi/document?reg=1061848202959, printed 8/25/03 (2 pages). C2 Anonymous, Heparin-coated stents cut complications by 30%, Clinica 732:17 (Nov. 18, 1996), http://www.dialogweb.com/cgi/document?reg=1061847871753, printed 8/25/03 (2 pages). C3 Anonymous, Rolling Therapeutic Agent Loading Device for Therapeutic Agent Delivery or Coated Stent (Abstract 434009), Res. Disclos. pp. 974-975 (June 2000). C4 Anonymous, Stenting continues to dominate cardiology, Clinica 720:22 (Sept. 2, 1996), http://www.dialogweb.com/cgi/document?reg=1061848017752, printed 8/25/03 (2 pages). Aoyagi et al., Preparation of cross-linked aliphatic polyester and application to thermo-responsive material, C5 Journal of Controlled Release 32:87-96 (1994). C6 Barath et al., Low Dose of Antitumor Agents Prevents Smooth Muscle Cell Proliferation After Endothelial Injury, JACC 13(2): 252A (Abstract) (Feb. 1989). Barbucci et al., Coating of commercially available materials with a new heparinizable material, J. Biomed. C7 Mater. Res. 25:1259-1274 (Oct. 1991).

C9 Dev et al., Kinetics of Drug Delivery to the Arterial Wall Via Polyurethane-Coated Removable Nitinol Stent: Comparative Study of Two Drugs, Catheterization and Cardiovascular Diagnosis 34:272-278 (1995). C10 Dichek et al., Seeding of Intravascular Stents with Genetically Engineered Endothelial Cells, Circ. 80(5):1347-1353 (Nov. 1989). Eigler et al., Local Arterial Wall Drug Delivery from a Polymer Coated Removable Metallic Stent: Kinetics, Distribution, and Bioactivity of Forskolin, JACC, 4A (701-1), Abstract (Feb. 1994). C12 Helmus, Overview of Biomedical Materials, MRS Bulletin, pp. 33-38 (Sept. 1991). C13 Herdeg et al., Antiproliferative Stent Coatings: Taxol and Related Compounds, Semin. Intervent. Cardiol. 3:197-199 (1998).

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Journal of Controlled Release 65:93-103 (2000).

Chung et al., Inner core segment design for drug delivery control of thermo-responsive polymeric micelles,

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FORM PTO-1449 (Modified)		US DEPARTMENT OF COMMERCE	Docket No.	Application No.		
Approved for use through 10/31/2002		US Patent and Trademark Office	50623.334	10/663,181		
INFO	RMATION DISCL	OSURE CITATION	Applicant			
	in an Appl	ication	Steven	Z. Wu		
	(Use several sheets	if necessary)	Filing Date September 15, 2003	Group Art Unit Unassigned		
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EXAMINER		DATE CONSIDER	ED			
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